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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/731,988 | 12/09/2003 | Surcsh K. Arya | 4239-67517 | 9402 |

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| EXAMINER | |
| HILL, MYRON G | |
| ART UNIT | PAPER NUMBER |
| 1648 | |

DATE MAILED: 09/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/731,988

Applicant(s)

ARYA, SURESH K.

Examiner

Myron G. Hill

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 7-9,11-15,17,21 and 43-50 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☐ Claim(s) 7,8,11-13,15,17,21,43-46,48 and 50 is/are rejected.
7) ☒ Claim(s) 9,14,44-46 and 49 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to the paper filed

Claims 7-9, 11-15, 17, 21, 43-46, and 48-50 are under consideration.

Rejections Withdrawn

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

Claims 7, 11, and 15 ^{were} ~~are~~ rejected under 35 U.S.C. 102(a) as being anticipated by Arya *et al.* (Human Gene Therapy 1998 Vol. 9, pages 1371-1380).

Applicant has provided a Katz type declaration and the rejection is withdrawn.

Claim Rejections - 35 USC § 103

Claims 7, 8, 11-13, 15, 17, 21, 43, 48, and 50 ^{were} ~~are~~ rejected under 35 U.S.C. 103(a) as being unpatentable over Arya *et al.* as applied to claims 7, 11, and 15 above, and further in view Verma *et al.* (US Pat 6013516 from IDS).

Arya *et al.* is no longer available as prior art (see above) and thus, the rejection is withdrawn.

Rejections Maintained

Claim Rejections - 35 USC § 103

Claims 7, 8, 11-13, 15, 17, 21, 43, 48, and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCann *et al.* and Verma *et al.* (US Pat 6013516).

Applicant argues that McCann *et al.* teach away from the deletion of both as well as neither reference teaches deletion of both upstream and downstream sequences.

Applicant's arguments have been fully considered and not found persuasive.

The art does not teach away from a combination. The reference is to the fact that the analogous mutations in HIV-1 result in a more dramatic reduction in packaging. One of ordinary skill in the art at the time of invention would have been motivated for at least two reasons to make the deletions upstream and downstream of the SD site. As taught in Verma *et al.* the genes are put on different vectors. One of ordinary skill in the art at the time of invention would have known that this is to reduce the risk of homologous recombination and thus would be motivated to eliminate extra sequences from the vectors. Also, knowing that both regions were involved in packaging one of skill in the art would be motivated to make deletions in both regions because the prior art teaches that it is desired to delete the packaging signal (see Verma *et al.* paragraph spanning columns 3-4 and Figure 1, constructs 1 and 2) and McCann *et al.* shows that packaging signals are both upstream and downstream of the SD.

Thus, the rejection is maintained.

Allowable Subject Matter

Claims 9, 14, 44-46, and 46 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 8:30 am-5 pm Mon-Fri.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Myron G. Hill
Patent Examiner
1 September 2006



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